FEB 26

510(k) Summary
Philips HeartStart SmartPads III
Multifunction Defibrillation Pads

1. **510(k) Submission Number:** K072812

2. **Date Summary Prepared:** February 22, 2008

3. **Submitter's Name and Address:**

   Philips Medical Systems
   2301 Fifth Avenue, Suite 200
   Seattle, WA 98121

4. **Contact Person:**

   Larry Walker
   Philips Medical Systems
   2301 Fifth Avenue, Suite 200
   Seattle WA 98121
   Telephone: (206) 664-5000
   Fax: (206) 664-5001

5. **Device Name:**

Proprietary Name:	Philips HeartStart SmartPads III Multifunction Defibrillation Pads
Common Name:	Multifunction Defibrillation Pad
Classification Name:	(MKJ) Automated External Defibrillator (Class III) (MLN) Multifunction Electrocardiograph Electrode (Class II)

6. **Predicate Device**

   The legally marketed device, to which Philips Medical Systems claims equivalence, is the Philips Medical Systems HeartStart SmartPads II Multifunction Defibrillation Pads, cleared as a part of the Philips Medical System HeartStart model FRx Automated External Defibrillator (K050004).

   The design and the intended use of the HeartStart SmartPad III is substantially equivalent in safety and performance to the device named above.

7. Device Description Summary

The Philips Medical Systems HeartStart SmartPads III is a disposable, self-adhesive, single use disposable defibrillator pad set, designed for external defibrillation, external pacing, cardioversion and monitoring with current and future Philips Medical Systems defibrillators. The SmartPads III are also compatible with other defibrillators through currently marketed Philips adapters.

The HeartStart SmartPad III consists of foam backing, laminated metallic substrate, conductive adhesive gel, cabling and molded connector. The SmartPad III are packaged in pairs within a water-vapor proof, heat sealed, non-transparent aluminized pouches.

8. Intended Use

The Philips HeartStart SmartPads III is indicated for external defibrillation, pacing, monitoring and cardioversion.

The SmartPads III is intended for adults and children over 8 years of age or greater than 55 pounds (25kg) with all compatible defibrillators. The SmartPads III is also indicated for children of all ages when used with a Philips Medical System model FRx equipped with an Infant/Child Key or with other compatible defibrillators which incorporate adjustable defibrillation energy functionality

9. Indications for use

The Philips HeartStart SmartPads III is indicated for external defibrillation, pacing, monitoring and cardioversion.

The SmartPads III is intended for adults and children over 8 years of age or greater than 55 pounds (25kg) with all compatible defibrillators. The SmartPads III is also intended for children of all ages when used with a Philips Medical System model FRx equipped with an Infant/Child Key or with other compatible defibrillators which incorporate adjustable defibrillation energy functionality.

The device is non-sterile and single-use only.

10. Comparison of Technology Characteristics

The Phillips HeartStart SmartPads III employs the same fundamental scientific technology as the currently available Philips HeartStart SmartPad II.

11. Data Used in Determination of Substantial Equivalence

Testing demonstrated the Philips HeartStart SmartPads III perform in a manner substantially equivalent to the predicate SmartPads II and is acceptable for its indicated use and meets the predefined criteria.

Testing demonstrated the performance of the SmartPads III is acceptable for its indicated use and the meets predefined criteria.

12. Conclusion

The proposed modifications do not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2008

Philips Medical Systems
c/o Mr. Larry Walker
Regulatory Affairs Specialist
2301 Fifth Avenue, Suite 200
Seattle, WA 98121

Re: K072812
Trade/Device Name: Philips Heartstart Smartpads III
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillators
Regulatory Class: III (three)
Product Code: MKJ, MLN
Dated: January 18, 2008
Received: January 22, 2008

Dear Mr. Walker:

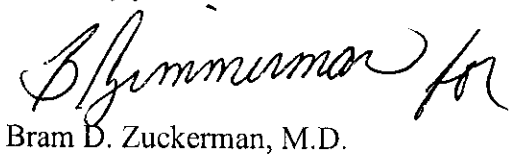
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11. Indications for Use

510(k) Number (if known): **K072812**

Device Name: Philips HeartStart SmartPads III Multifunction Defibrillator Pads

Indications For Use:

The Philips HeartStart SmartPads III is indicated for external defibrillation, pacing, monitoring and cardioversion.

The SmartPads III is intended for adults and children over 8 years of age or greater than 55 pounds (25kg) with all compatible defibrillators. The SmartPads III is also intended for children of all ages when used with a Philips Medical System model FRx equipped with an Infant/Child Key or with other compatible defibrillators which incorporate adjustable defibrillation energy functionality

The device is non-sterile and single-use only.

Prescription Use ___X___ or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072812